PREDICT

Briefing Slides for Importers and Entry Filers

FDA Office of Regulatory Affairs
Office of Resource Management

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Topics

- Purpose of PREDICT, relationship to OASIS and MARCS
- Overview of import processing workflow
- PREDICT methods, screening rules, risk types
- Pilot test and production rollout
- Violation rates vs. PREDICT screening results
- Automated system “May proceed” rates
- Entry data quality, and why it really matters with PREDICT

OASIS and MARCS

- OASIS
  - Operational and Administrative System for Import Support
  - Legacy imports system operating 24/7 FDA-wide since 1998.
- MARCS
  - Mission Accomplishments and Regulatory Compliance Services – import and domestic
  - Under construction. MARCS Imports will eventually replace all of OASIS.
  - MARCS Entry Review is currently replacing the entry review application (only) from OASIS.

PREDICT

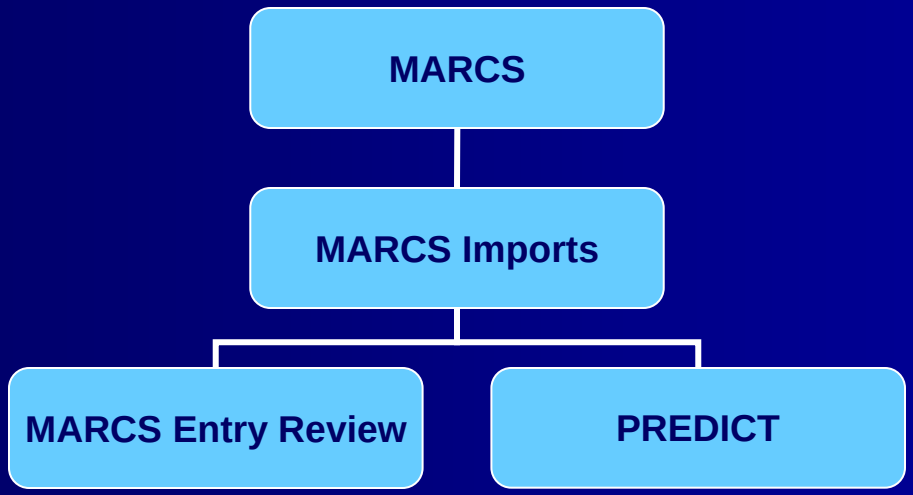
- Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting
- Replaces the electronic screening function of OASIS for import admissibility determinations.
- Purpose ---

  Improve import screening and targeting to ---

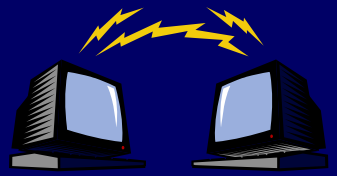
  - Prevent the entry of adulterated, misbranded, or otherwise violative goods
  - Expedite the entry of non-violative goods

PREDICT is not MARCS Entry Review

- PREDICT functions mostly behind the scenes.
- MARCS Entry Review replaces the legacy entry review screens from OASIS.
- Entry reviewers have access to PREDICT screening results through a “mash-up” within MARCS Entry Review.



Electronic Transactions Import Entry Lines



OASIS

PN screening – food

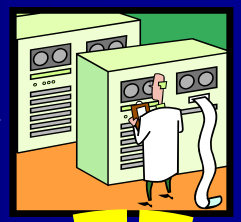
Entry filer

Firms, product code

Customs

foods

others

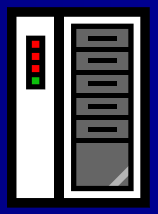


Prior Notice Center

foods

PREDICT

Admissibility screening



Yes

OK?

No

"FDA review" message

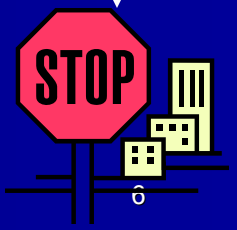
"May proceed" message

FDA district entry reviewer

No

Review?

Yes



District entry reviewer using MARCS Entry Review

Documents requested by FDA

Initial action?

OASIS

Field exam

???

Results?

Good

Bad

Sample, analyze

OASIS

"May proceed" message

Detain w/o physical exam

Detain

Release with comment

Release

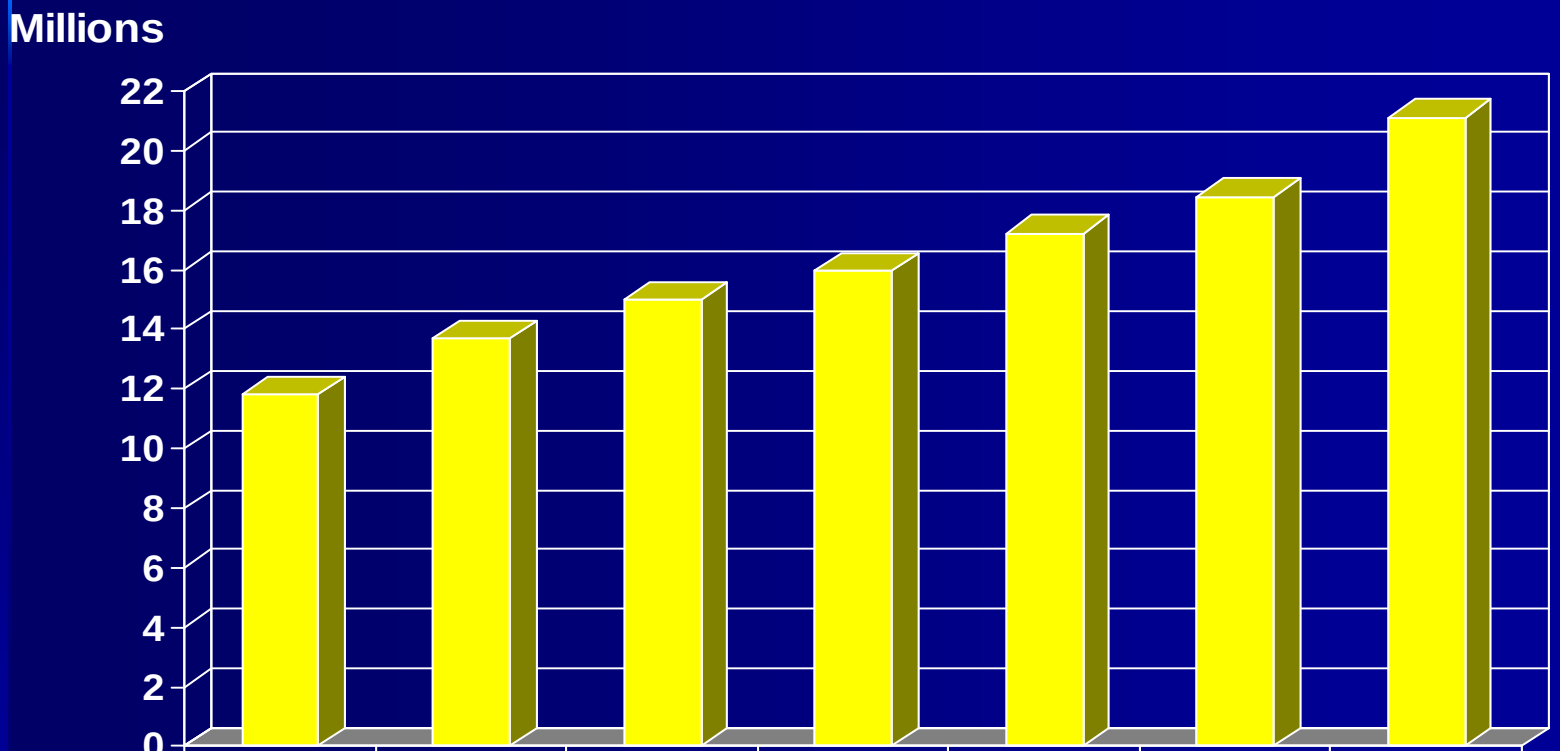
IB release

Compliance action

Entry filer

Compliance Officer

Workload: Import entry lines, in millions (excluding mail and baggage)



	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Lines	11,820,000	13,700,000	14,980,000	15,960,000	17,210,000	18,460,000	21,124,000

PREDICT purpose and method

- Improve the targeting of entry lines by –
  - Scoring each entry line on the basis of a wide range of risk factors
  - Increasing the number of automated, real-time, “may proceed” decisions for lower-risk lines, thereby giving entry reviewers more time to evaluate the higher-risk lines
  - For those lines not given an automated “may proceed,” providing reviewers with the scores and the reasons for those scores

PREDICT purpose and method

- Using automated data mining and pattern discovery for rules development
- Utilizing open-source intelligence
- Providing automated queries of Center databases where relevant (i.e., registration and listing, marketing approval status, low-acid canned food scheduled processes, etc.)

2 of 2

Examples of source data for PREDICT screening rules

- Ratings of inherent product risks
- Results of field exams and sample analyses from previous entries
- Results of facility inspections, foreign and domestic
- Accuracy of product and facility coding by entry filers and importers

Examples of source data for PREDICT screening rules

- Data anomalies within the current entry
- Admissibility history with respect to the manufacturer, exporter, importer, and consignee for the current product (at industry and more specific levels)
- Open source intelligence pertaining to the manufacturer, foreign locale, product, etc.

2 of 2

Risk types to be included in targeting scores

- Compliance risk (probability of violation)
- Product-related
  - Inherent health risk (Type 1)
  - Incremental health risk in view of previous FDA analytical results for products of the same manufacturer (Type 2)
  - Risk of the product being the target of economic adulteration with hazardous consequences; i.e., wheat flour or milk adulterated with melamine and cyanuric acid; counterfeit drugs with missing or different inactive ingredients, etc. (Type 3)

Pilot test

- Prototype PREDICT application
- Conducted during the summer of 2007
- Covered 32,696 entry lines of seafood entering at five ports within Los Angeles District
- In comparison to the legacy system ---
  - Violation rates for field exams and sample collections were substantially higher
  - Health significance of the violations found was greater
  - The automated “may proceed” rate was substantially higher, thereby expediting the entry of lower-risk products

Timeline: Production rollout

-- All products, all FDA Centers --

Sept. 25, 2009	Los Angeles District rollout
February 2010	Abrupt, serious slowdown of all field IT applications nationwide -- legacy & modern, domestic & import
Early March 2010	New York District rollout
Late March 2010	Further rollout on HOLD due to IT infrastructure and MARCS Entry Review application performance issues. Without that application, reviewers cannot see data from PREDICT.
Summer 2010	Troubleshooting done under contract by MITRE Corp. Some improvements made to the network and to the configuration of the field PCs. Migration of agency enterprise systems to contractor-hosted data center begins.

Timeline: Production rollout

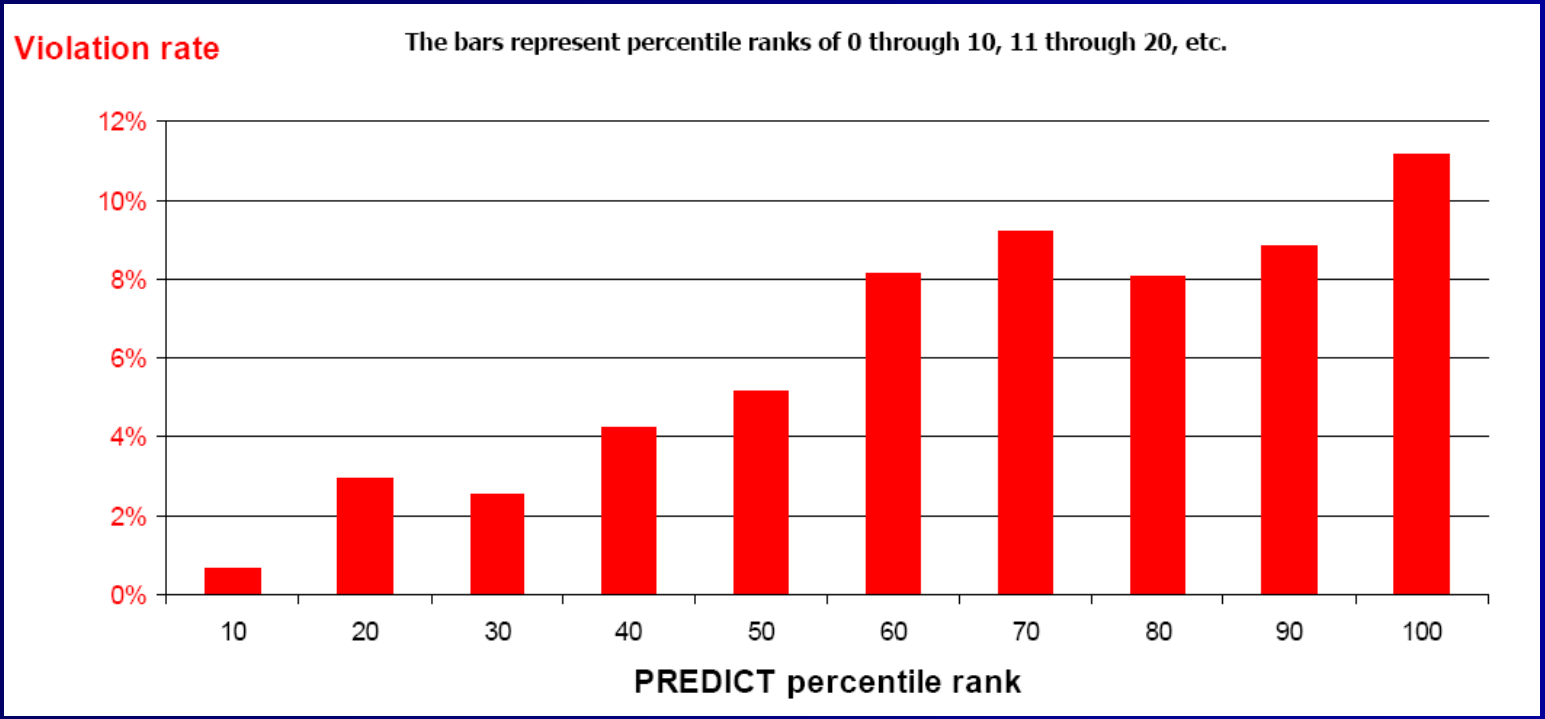
-- All products, all FDA Centers --

Sept. 21, 2010	Rollout resumes with the training of users in Seattle and San Francisco Districts
October 2010	PREDICT is running well, but the Entry Review application remains agonizingly slow.
Mid-March 2011	A problem with server environment settings is found and fixed. This dramatically improves the performance of MARCS Entry Review. Users rejoice.
April 2011	Nationwide rollout resumes successfully at Florida and San Juan Districts, followed by Atlanta and Minneapolis Districts.
May 2011	*System to be deployed to New Orleans, Philadelphia, Cincinnati, Detroit, Chicago, and Baltimore Districts.*
June 2011	*System to be deployed to New England and Southwest Imports Districts. Nationwide rollout will be complete.*

Violation rate: Field and label exams

81,480 field and label exams for entries submitted Oct 2009 through Nov 2010

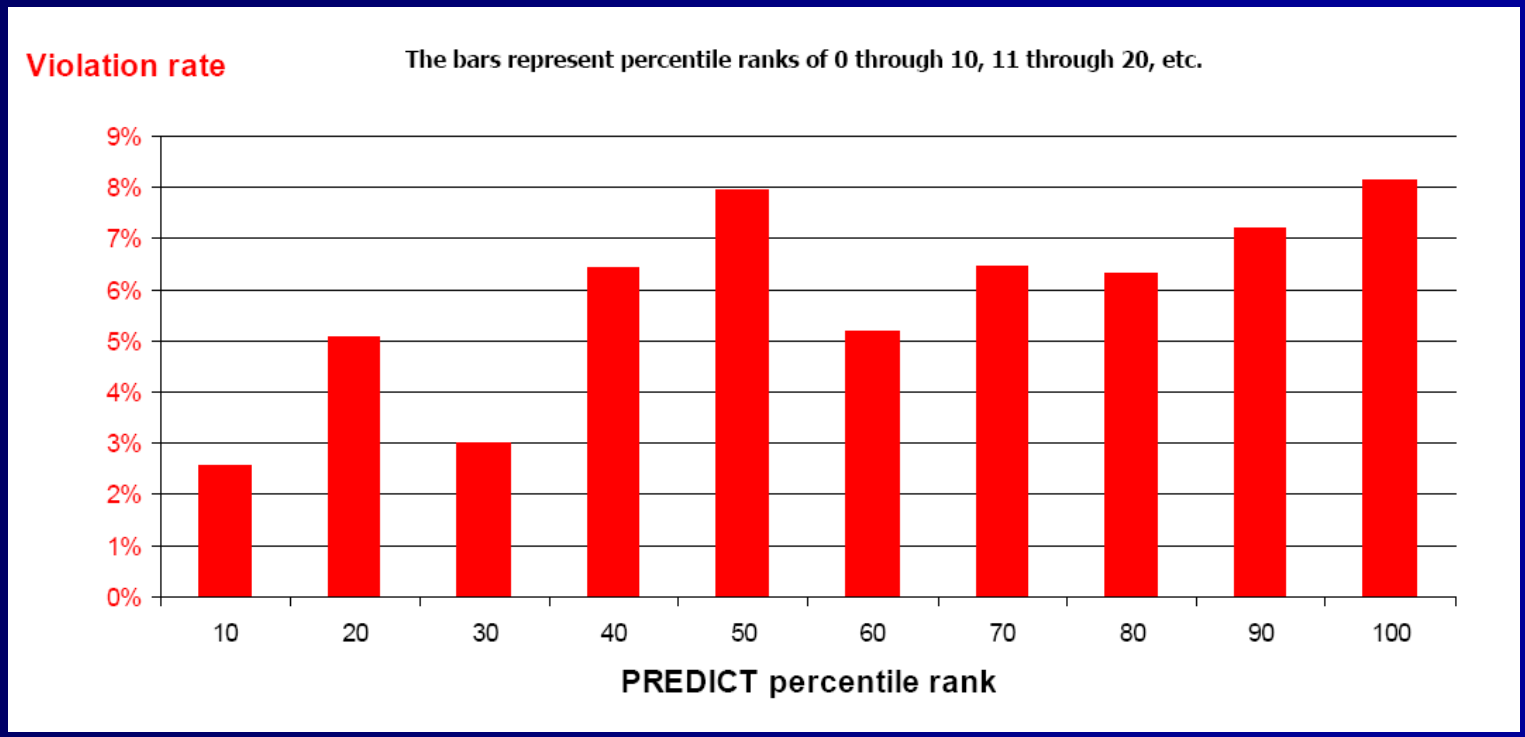
The higher the PREDICT targeting score, the more likely the violation.



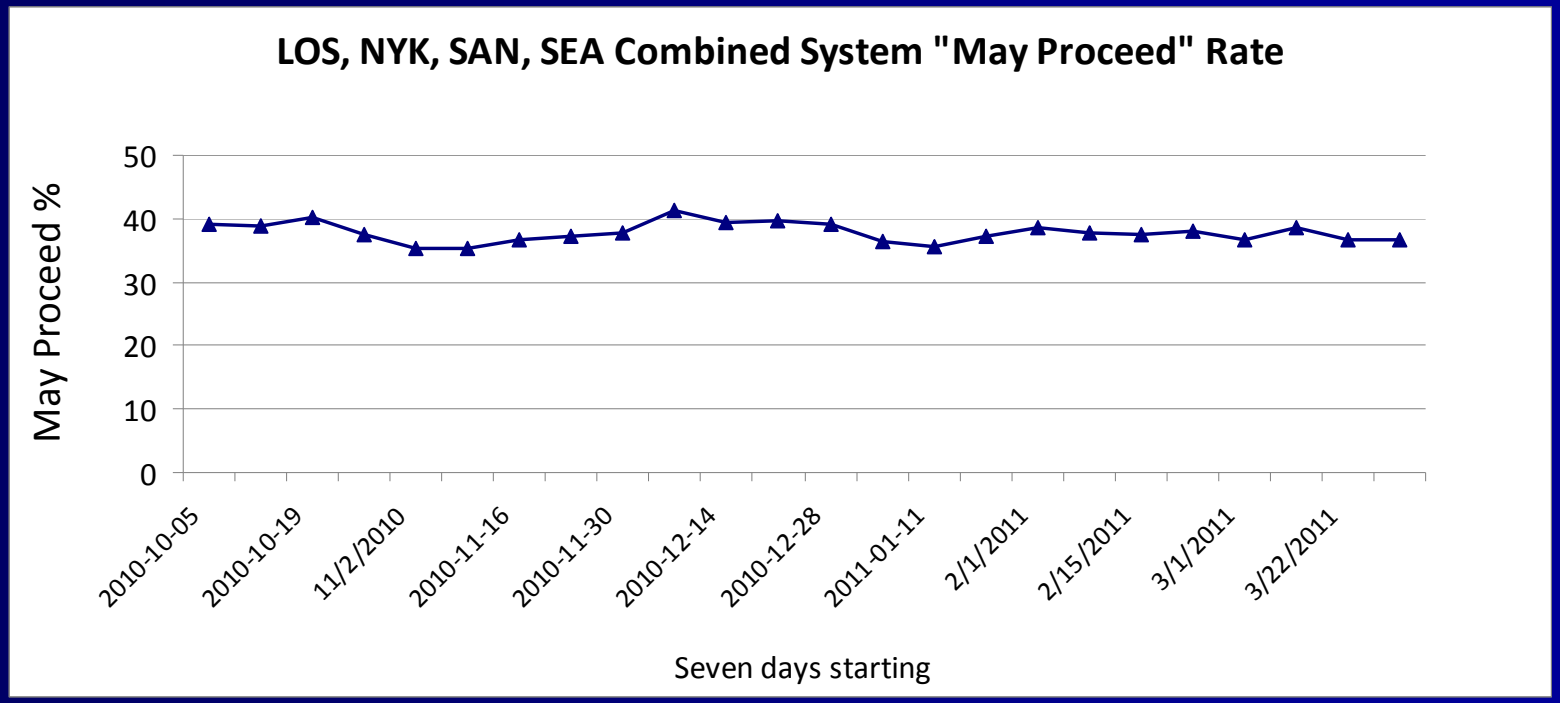
Violation rate: Samples analyzed

11,282 sample collections for entries submitted Oct 2009 through Nov 2010

The higher the PREDICT targeting score, the more likely the violation.



Expedited release of lower-risk shipments



Note: Nearly all drug and medicated feed entry lines are being held for marketing status lookups by entry reviewers. Those lookups are not yet automated by PREDICT.

Automated system "may proceed" rates

Examples by type of product

Examples	Rates as of March 29, 2011
Human foods	39.5%
Housewares & food-related	86.5%
Cosmetics	23.5%
Medical devices	15.2%
Drugs	3.2%

- Electronic screening standards are uniform nationally.
- Automated database lookups have not yet been implemented for drugs or medicated feeds.

Efficiency

- PREDICT improves the efficiency of entry review. It automatically clears about three times as many entry lines of lower-risk products as does the legacy system. This substantially reduces entry reviewer workload, allowing reviewers to devote more time to targeting higher-risk products.
- PREDICT performs automated queries of Center databases for issues such as registration, listing, and product approval, and it furnishes entry reviewers with the results as appropriate. This function has been implemented for medical devices, electronic products, and low-acid canned foods. It will be implemented for drugs later this year.

Affirmations of compliance

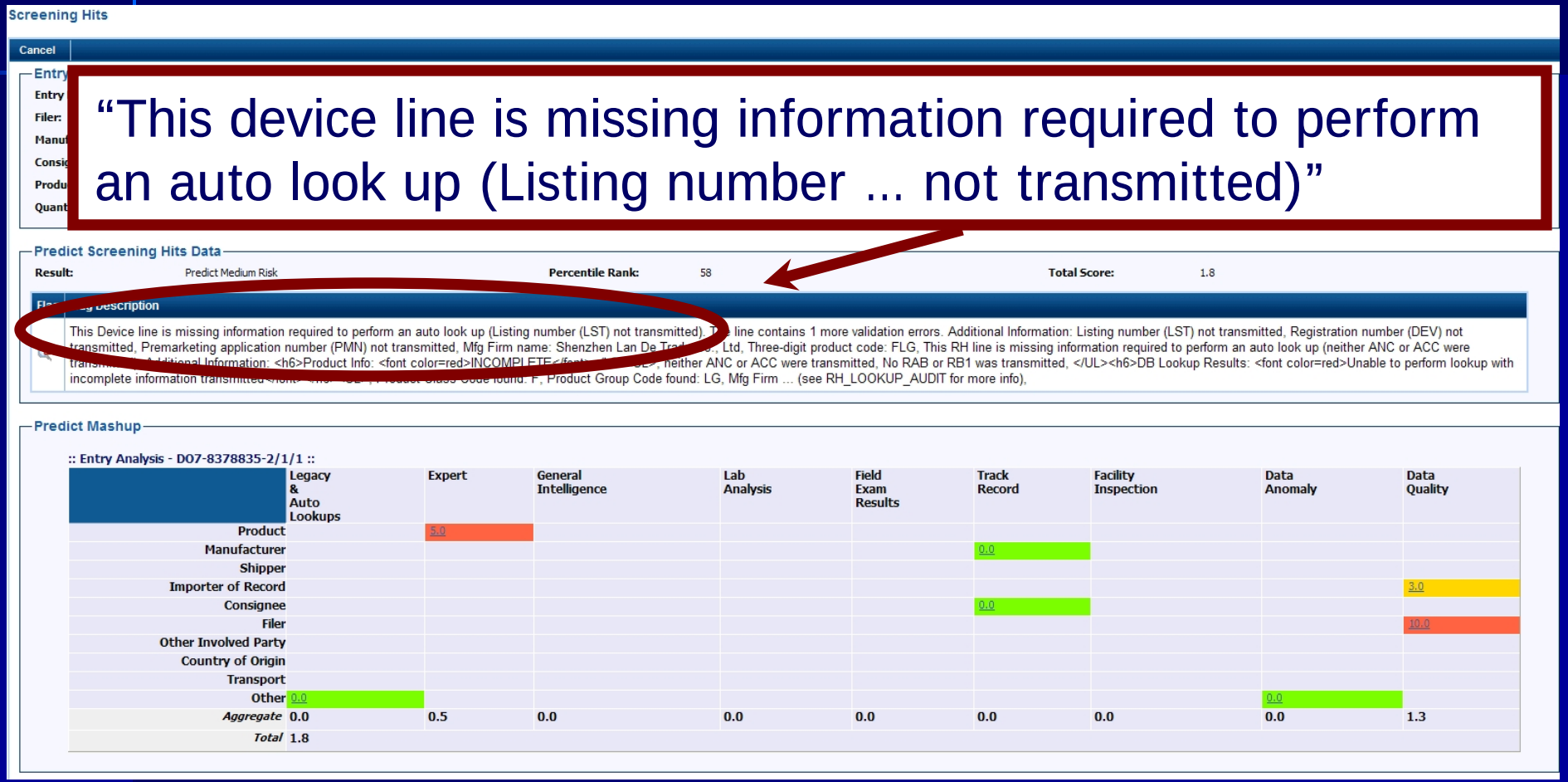
- Affirmations of compliance are data elements submitted voluntarily to FDA to expedite the entry review process. For example:
  - New drug application number
  - Device 510(k) clearance number
  - National drug code (NDC)
  - Radiological health product report accession number

Needed from entry filers:

Accurate, consistent, complete data

- To expedite entry screening by PREDICT, importers and entry filers must provide:
  - Consistent, accurate identifiers for firms
  - Accurate product codes
  - All of the relevant affirmations of compliance
- With those data PREDICT will be able to issue system 'may proceeds' quickly for lines with lower targeting scores
- OASIS tracks FDA corrections of data submission errors, and PREDICT uses these data to adjust the targeting scores for future entry lines

PREDICT automated database lookup not performed because the filer did not submit necessary data



With PREDICT:
Affirmations of compliance

- With accurate and complete affirmations of compliance (NDA, ANDA, PMA, 510(k), NDC numbers, etc.), PREDICT will be able to do the automated lookups for marketing status.
- If an automated lookup fails, the entry line will be forwarded to a reviewer for manual processing.

Entry reviewer workload

Entry lines not given a "may proceed" by PREDICT go to an entry reviewer for manual processing.

"In" box

MID

Customs' manufacturer identification

- Receiving inconsistent MIDs for the same foreign facility is a serious data quality issue for FDA.
- Typical: 6 different MIDs for one facility. Current record: >100.
- The lack of a reliable, truly unique identifier seriously undermines the targeting process, and can enable shipments to evade import alerts and bulletins.
- Submitting a new MID for an established facility will often cause PREDICT to view the facility as new, and the targeting score will be substantially elevated.
- The long-term solution is to replace the MID with a unique, reproducible identifier.

Importers and Filers

- With PREDICT the quality of the data you submit to FDA counts more than ever.
- Importers need to work closely with filers to ensure data quality.
- Poor data quality or missing data will increase the targeting scores for your subsequent entry lines (importers and filers).
- Higher targeting scores increase the likelihood of examination and/or sampling by FDA.
- Data error rates are available to the public through the Freedom of Information Act.

Questions?